

Applicant: Bonutti et al.
Application No.: 10/760,598
Examiner: M. Brown

REMARKS

Claims 1-23 are pending in the application and are presented for the Examiner's review and consideration. Claims 1, 3, 15, and 23 have been amended. Applicants believe that the claim amendments and the accompanying remarks serve to clarify the present invention and are independent of patentability. Accordingly, Applicants respectfully submit that they do not limit the range of any permissible equivalents.

35 U.S.C. § 103(a)

Claims 1-3, 6-9, 12-18, and 20-23 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,407,420 to Bastyr et al. ("Bastyr") in view of U.S. Patent No. 5,417,643 to Taylor ("Taylor"). For the reasons set forth below, Applicants respectfully submit that the rejected claims are patentable over Bastyr in view of Taylor.

Bastyr discloses a fully adjustable orthopedic shoulder brace for stabilizing and immobilizing the shoulder of a patient. (Col. 2, lns. 12-14). The shoulder brace maintains the shoulder relatively comfortably and unobtrusively in a fixed, yet adjustable, position that facilitates rehabilitation of the shoulder throughout the healing period, and particularly during the acute rehabilitation phase immediately following an injury or surgery. (Col. 2, lns. 18-24). The body-mounted brace is fully adjustable across the three ranges of motion of the shoulder, i.e., abduction, flexion and rotation, to enable fixation of the shoulder in virtually any rehabilitative position. (Col. 2, lns. 28-31).

The brace 10 is mounted on the body 12 by means of a support assembly comprising a plurality of cuffs, including a hip cuff 16 formed from a stiffened sheet of plastic that is nevertheless sufficiently flexible to conform to the contour of the hip 18 engaged by the cuff 16. (Col. 4, lns. 22-27). A padded belt 22 is tightly fastened around the midsection of the patient over the hip cuff 16 and pad 20, thereby pressing the cuff 16 and pad 20 firmly against the hip 18 in conformance therewith to secure the brace 10 at the hip 18. (Col. 4, lns. 32-36). An upper

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arm cuff 28 is provided to engage the upper arm 24. (Col. 4, lns. 40-41). A forearm cuff 36 is provided to engage the forearm 26. The forearm cuff 36 is formed from a rigid sheet of metal that is preformed to conform to the body contours engaged by the cuff 36. (Col. 4, lns. 57-58).

The above-described cuffs 16, 28, and 36 are interconnected by means of a plurality of rigid support members joined across a plurality of selectively rotatable and lockable joints. (Col. 5, lns. 9-12). A joint assembly 70 proximally joins the torso bar 48 to the upper arm linkage 54 at the anterior of the body 12 near the axilla 52. (Col. 5, lns. 38-40). The joint assembly 70 comprises a shoulder abduction joint 72 at the proximal end of the torso bar 48 and a shoulder flexion joint 74 at the proximal end of the upper arm linkage 54. (Col. 5, lns. 40-43). A shoulder rotation joint 78 integral with the upper arm linkage 54 is further to rotatably connect the female bar 60 and the male bar 62. (Col. 5, lns. 44-46). Finally, an elbow flexion joint 80 joins the distal end of the upper arm linkage 54 to the proximal end of the forearm bar 64 at the underside of the elbow 58. (Col. 5, lns. 47-50). The elbow flexion joint 80 rotatably connects the forearm bar 64 and upper arm linkage 54, and enables selective locking of the joint 80 in a desired angle of elbow flexion. (Col. 7, lns. 40-43).

The shoulder rotation joint 78 is distinguishable from the joints 72, 74, and 80 described above insofar as the joint 78 is integral with the upper arm linkage 54. (Col. 9, lns. 18-20). As such, the axis of rotation of the joint 78 is collinear with its adjacent support member 54, whereas the axes of rotation of the remaining joints 72, 74, and 80 are perpendicular to the respective adjacent support members 48, 54, or 64. (Col. 9, lns. 20-25).

As such, Bastyr discloses an orthopedic shoulder brace worn on the body of a patient and for stabilizing and immobilizing a shoulder of a patient. The brace is affixed to the torso, upper arm, and forearm of the patient with cuffs. A plurality of joint assemblies interconnect the cuffs, allowing the brace to be adjusted to fix the shoulder in virtually any position. The joints assemblies include a shoulder abduction joint, a shoulder flexion joint, a shoulder rotation joint, and an elbow flexion joint. The elbow flexion joint allows the forearm to adjustably positioned with respect to the upper arm in flexion. The shoulder rotation joint is integral with an upper arm

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linkage, such that the axis of rotation of the joint is collinear with its adjacent support member. The axes of rotation of the remaining joints are perpendicular to the respective adjacent support members.

Taylor relates to a physical therapy device useful in the treatment of infirmities of the arms and shoulders. (Col. 1, lns. 6-8). Specifically, this invention relates to a physical therapy device that permits a user's arms to be treated by elevation, that is, by flexion and extension, in the scapular plane, and by external and internal rotation, i.e., movement of the arms transverse to the scapular plane. (Col. 1, lns. 11-16). It is a first aspect of this invention to provide an improved continuous passive motion exercise device. (Col. 2, lns. 36-37). Yet an additional aspect of this invention is to provide a continuous passive motion exercise device capable of exercising an individual's arm in one of two separate motions; in two different motions conducted simultaneously; or in two different motions performed sequentially. (Col. 2, lns. 57-62).

A motivator assembly, generally 18, is attached to a patient treatment chair, generally 12. (Col. 3, lns. 54-56). The motivator assembly 18 has an elevation drive unit 20 adjustably mounted to support bracket 22. (Col. 3, lns. 61-62). Elevation pivot arms 28 are further connected to the elevation drive unit 20, and at their lower end are connected to a rotation drive unit 30 through a connecting bracket 29, better seen in FIG. 2. (Col. 3, lns. 62-66). Connected to rotation drive unit 30 is a rotation pivot arm 40 to which is pivotally connected an orthosis cradle, generally 32. (Col. 3, lns. 66-68). The orthosis cradle 32 comprises a base member 31, one end of which is bent at an angle θ to accommodate the patient's forearm and a portion of the upper arm. (Col. 3, ln. 68 - col. 4 ln. 3).

The elevation drive unit 20 enables the device to move a patient's arm through a range of motion extending from about 30 degrees, at which point the patient's upper arm lies at an angle of about 30 degrees relative to the longitudinal axis of the patient's upper torso, i.e., a position in which the upper arm lies substantially at the patient's side, to an angle of about 180 degrees, at which point the arm has been elevated to approximately an overhead position. (Col. 4, lns. 43-

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51). With respect to the rotation drive 30, the unit is capable of rotating the patient's forearm located in the orthosis cradle 32 through an arc of about 90 degrees. (Col. 4, lns. 53-55). Such rotation is transverse to the patient's scapular plane and can extend inwardly, internally, about 45 degrees, or outwardly, externally, for about 45 degrees from a neutral plane in which the orthosis is positioned. (Col. 4, lns. 62-66).

As such, Taylor discloses a continuous passive motion device, in which the user is seated, for use in the treatment of infirmities of the arms and shoulders. The device includes a pair of interconnected drive units, an elevation drive unit and a rotational drive unit connected to a chair. The elevation drive unit enables the patient's arm to be elevated from a position proximal to the torso of the patient to a fully extended over head position. The rotation drive unit rotates the patient's arm through an arc which traverses the patient's scapular plane. The elevation drive unit and the rotation drive unit work in concert to continuously move the patient's arm through the therapeutic range of motion.

Initially, Applicants submit that Bastyr is not analogous prior art. "In order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned." *In re Oetiker*, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). See also *In re Deminski*, 796 F.2d 436, 230 USPQ 313 (Fed. Cir. 1986); *In re Clay*, 966 F.2d 656, 659, 23 USPQ2d 1058, 1060-61 (Fed. Cir. 1992).

In the present invention, the inventors' endeavors is towards a shoulder orthosis device for effecting rotational movement of a lower arm portion about a central longitudinal axis of a humerus bone of an upper arm portion of an arm of a patient. The device utilizes a lower arm section configured for receiving the lower arm portion, where the lower arm section maintains the lower arm portion substantially orthogonal to the upper arm portion. A drive member is operably connected to the lower arm section to rotate the lower arm portion about the central longitudinal axis of the humerus bone. In contrast, Bastyr is directed towards an orthopedic shoulder brace for stabilizing and immobilizing (fixation) a shoulder of a patient. As such, a

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shoulder brace for fixation of a shoulder is not reasonably pertinent to the particular problem with which the inventors were concerned, namely, providing an orthosis for effecting rotational movement of a lower arm portion about a central longitudinal axis of the humerus bone of an upper arm portion of a patient's arm.

Furthermore, to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). MPEP §2142.

The Examiner stated that the first and second drive units as taught by Taylor could be substituted for the drive mechanism disclosed by Bastyr because the four drive mechanisms are interchangeable. For the reasons set forth below, Applicants respectfully traverse this combination of references.

Applicants note that there is no motivation to combine the references, either in the references themselves or to one of ordinary skill in the art. As noted above, Bastyr is directed towards a wearable brace for stabilizing and immobilizing a shoulder whereas Taylor is directed towards continuous passive motion exercise device that a user sits in and treats an arm of the user by elevation, that is, by flexion and extension, in the scapular plane, and by external and internal rotation, i.e., movement of the arms transverse to the scapular plane. As such, Bastyr and Taylor are directed towards opposing forms of treatment, namely, immobilization verses continuous passive motion. Accordingly, there is no explicit or inherent disclosure to modify the references or to combine teachings of the references.

Additionally, there is no reasonable expectation of success in combining the references. Bastyr discloses that a plurality of joint assemblies interconnect the cuffs, allowing the brace to

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be adjusted to stabilize and immobilize the shoulder. In contrast, Taylor discloses interconnected drive units, namely, an elevation and a rotation drive unit, which work in consort to continuously move the patient's arm in a therapeutic range of motion. As such, the inclusion of the Taylor drive unit in the Bastyr device would defeat the purpose of the device, namely, an immobilization of the shoulder.

Furthermore, Bastyr discloses that the shoulder rotation joint is distinguishable from the other joints insofar as the shoulder rotation joint is collinear with its adjacent support member, whereas the axes of rotation of the remaining joints are perpendicular to the respective adjacent support members. In contrast, in Taylor the elevation drive unit enables the patient's arm to be elevated from a position proximal to the torso of the patient to a fully extended over head position and the rotation drive unit rotates the patient's arm through an arc which traverses the patient's scapular plane. As such, the Bastyr joints and the Taylor drive units perform different functions and exhibit different, non-interchangeable, movements in performing these functions.

Finally, the Bastyr device is a mobile device to be continuously worn by the patient. The Taylor device is a bulky exercise device, in which the patient sits. The device is not a mobile device intended to be continuously worn by the patient. As such, there is no indication that the Taylor drive units can be successfully incorporated into the Bastyr device.

Additionally, the references do not teach or suggest all the claim elements even if combined as suggested. The Examiner stated that Bastyr discloses in Figures 1-4b shoulder orthosis comprising a lower arm section 64, a drive member (54, 56), a lower cuff 36, hand cuff 42, the drive mechanism is rotated manually and rotates the lower arm section from different position.

Bastyr discloses a rigid metal upper arm linkage 54 attached to the upper arm cuff 28 in a freely rotatable manner by means of a rotatable mounting assembly 56. (Col. 5, lns. 20-22). The linkage 54 extends away from the axilla 52 along the underside of the upper arm 24 to the elbow 58. (Col. 5, lns. 22-24). The linkage 54 comprises a female bar 60 having a male bar 62 extending therefrom to provide telescopic adjustment of the length of the linkage 54 in a manner

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described hereafter, thereby enabling fitting of the brace 10 to different arm lengths. (Col. 5, lns. 24-29). A shoulder rotation joint 78 integral with the upper arm linkage 54 is further to rotatably connect the female bar 60 and the male bar 62. (Col. 5, lns. 45-47).

As such, the upper arm linkage 54 is attached to the upper arm cuff and extends to the elbow. The upper arm linkage 54 includes the shoulder rotation joint 78. Therefore, Bastyr's device rotates the lower arm of the patient about the upper arm linkage which is positioned below the upper arm.

In contrast, the present invention discloses a drive member that is operably connected to the lower arm section to rotate the lower arm portion about the central longitudinal axis of the humerus bone of the upper arm portion. Such a drive unit is not disclosed in Bastyr.

In sum, Bastyr rotates the lower arm about an axis located a distance from the humerus bone, while Applicants rotate the lower arm about the central longitudinal axis of the humerus bone.

Claim 1 now recites, *inter alia*, a shoulder orthosis device for effecting rotational movement of a lower arm portion about a central longitudinal axis of a humerus bone of an upper arm portion of a patient's arm. The orthosis includes a lower arm section configured for receiving the lower arm portion. The lower arm section maintains the lower arm portion substantially orthogonal to the upper arm portion. A drive member is operably connected to the lower arm section to rotate the lower arm portion about the central longitudinal axis of the humerus bone, while maintaining the lower arm portion substantially orthogonal to the upper arm portion. Claims 15 and 23 include similar recitations.

The combination of Bastyr and Taylor fails to disclose a drive member which is operably connected to the lower arm section to rotate the lower arm portion about the central longitudinal axis of the humerus bone. In the Office Action, the Examiner stated that it would have been obvious to one of ordinary skill in the art to substitute the drive mechanisms of Bastyr for the drive mechanisms of Taylor because the drive mechanisms are interchangeable. Whether this is true or not, Applicants contend that substituting the drive mechanisms fails to overcome the

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deficiencies of Bastyr. As previously described, Bastyr rotates the upper arm about an axis spaced a distance away from the humerus bone of the upper arm. Even if Taylor's drive mechanisms are used with Bastyr's device, the axis of rotation of the upper arm is still located a distance from the humerus bone. In contrast, Applicants rotate the upper arm about the central longitudinal axis of the humerus bone.

In light of the foregoing, independent claims 1, 15, and 23 are respectfully submitted to be patentable over Bastyr in view of Taylor. As claims 2, 3, 6-9 and 12-14 depend from claim 1 and claims 16-18 and 20-22 depend from claim 15, and necessarily include all the elements of their base claims, Applicants respectfully submit that these dependent claims are also patentable at least for the same reasons.

Claims 4, 5, 10, 11, and 19 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Bastyr in view of Taylor in further view of U.S. Patent No. 5,538,499 to Schween et al. ("Schween"). For the reasons set forth below, Applicants respectfully submit that the rejected claims are patentable over Bastyr in view of Taylor in further view Schween

As noted above claims 1 and 15 are submitted to be patentable over Bastyr in view of Taylor. The inclusion of Schween fails to overcome the deficiencies in Bastyr and Taylor. As claims 4, 5, 10 and 11 depend from claim 1 and claim 19 depends from claim 15, and necessarily include all the elements of their base claims, Applicants respectfully submit that these dependent claims are also patentable at least for the same reasons.

In light of the foregoing, claims 4, 5, 10, 11, and 19 are respectfully submitted to be patentable over Bastyr in view of Taylor in further view Schween.

Conclusion

In light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

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No fee is believed to be due. However, please charge any required fees (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 503410 (Docket No. 782-A04-006-3).

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'P.D.B.', followed by a long horizontal line extending to the right.

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